



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

AUG 19 2013

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Mrs. Kimberlee Young, Consultant/Agent for ConSeal International, Inc.
RegWest Company, LLC
8203 West 20th Street, Suite A
Greeley, CO 80634-4696

Subject: FQPA Code 302 Label Amendment
Product Name: *SaniCide*TM - 2
EPA Registration Number: 58300-19
Application Date: May 31, 2013
Application Received Date: June 3, 2013

Dear Mrs. Young:

This acknowledges receipt of your Label Amendment application, submitted pursuant to registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) 3(c) 5, as amended.

Pesticide Application:

ConSeal International, Inc. is electing to delete from the Product Label all references to "fogging" and adding the phrase "This product may be applied only by the methods specified on the labeling." The Product Label does not bear directions for Misting, nor is it an adjunct Product.

On Page Two:

Inserted the sentence, "This product may be applied only by the methods specified on the labeling." underneath the subheading "Directions For Use," Deleted "or fogging" twice in Item No. 3 in the subsection entitled "Product Information."

On Page Three:

Deleted "or fog," "or fogging," and "fogging" from "To Control Mold- and Slime-Forming Bacteria on Walls, Floors, Ceilings and Post-Crop Mushroom Growing Surfaces" Use Directions.

On Page Four:

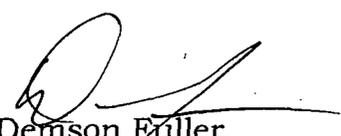
Deleted "or fog" from "To Disinfect Walls, Ceilings and Floors:" Use Directions.

General Comments:

Based on the review of the information submitted, the following comment applies. The Label Amendment is **Acceptable**. An EPA-stamped, **Accepted** Product Label is enclosed for your Company records. And an EPA-stamped, **Accepted** Product Label is attached in **Regulatory File Jacket 58300-19** for future reference. This labeling supersedes all previously accepted labeling. The next label printing off this Product must use this labeling unless subsequent changes have been approved. You must submit one (1) copy of the final printed labeling before you release the Product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this Product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this Product if it bears the new revised labeling or subsequently approved labeling "To distribute or sell" is defined under FIFRA section 3 (gg) and its implementing regulation 40 CFR 152.3.

If you have questions or comments with regard to this Agency Letter, the please contact Killian Swift via email at **Swift.Killian@epa.gov** or by telephone at **703-308-6346**. When you are submitting information or data in response to this Agency Letter, please send a copy of this Agency Letter with your response in order to facilitate processing.

Sincerely yours,



Demson Fuller,
Acting EPA Product Manager 32
Regulatory Management Branch II
Antimicrobials Division 7510P

Enclosure: EPA-stamped, **Accepted** "SaniCide™- 2" Product Label.

ACCEPTED
AUGUST 19, 2013
Under the Federal Insecticide, Fungicide, and
Rodenticide Act as amended, for the
pesticide, registered under
EPA Reg. No. 58300-19

SaniCide™-2

2% Aqueous Stabilized Chlorine Dioxide

Mushroom and Vegetable Rinse Applications
Disinfectant/Deodorizer/Slimicide

Biological Control in Paper Mills, Food Processing Flumes, Water Treatment Equipment, Petroleum
Recovery, Hospital Disinfecting, Cutting Oils, Cooling Towers and
Hard Surface Disinfection/Sanitation of Food Processing Equipment

For Institutional or Industrial Use

Active Ingredient:

Chlorine Dioxide	2%
Other Ingredients	98%
Total	100%

Keep Out of Reach of Children

CAUTION

See side panel for First Aid and additional Precautionary Statements.

EPA Reg. No. 58300-19

EPA Est. 58300-MA-1

Net Contents: ____ gal [oz.]
{5 through 55 gals.}

{Side Panels}

First Aid

If Swallowed:	<ul style="list-style-type: none"> • Immediately call a poison control center or doctor for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Do not give anything by mouth to an unconscious person.
If on Skin or Clothing:	<ul style="list-style-type: none"> • Take off contaminated clothing. • Immediately rinse skin with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
If in Eyes:	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
If Inhaled:	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth if possible. • Call a poison control center or doctor for further treatment advice.

Have the product container or label with you when calling a poison control center or doctor or when going for treatment. [You may also contact {phone number} for emergency medical treatment information.]

Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.

{Note: The First Aid statements' grid format will be used only if market label space permits; otherwise a paragraph format will be used.}

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION: Causes moderate eye irritation. Harmful if swallowed or absorbed through skin. Avoid contact with skin, eyes or clothing. Thoroughly wash with soap and water after handling.

Physical or Chemical Hazards

Stabilized chlorine dioxide is a strong oxidizing agent. Contamination with other materials such as acids, chlorine, organic chemicals, etc. may cause a chemical reaction, resulting in evolution of chlorine dioxide gasses and heat. Explosion and/or fire could result. Chlorine dioxide is a poisonous explosive gas. Keep all chemical and foreign materials away from this solution.

Environmental Hazards

This product is toxic to fish and aquatic organisms. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other public waters unless in accordance with the requirements of a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance contact your State water board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

This product may be applied only by the methods specified on the labeling.

Product Information

Refer to **Product Data** section before using this product in the generation of chlorine dioxide for biological control in Mushroom/Vegetable Processing/Canning operations and Biological Control in Paper Mills, Food Processing Flumes, Water Treatment Equipment, Petroleum Recovery, Hospital Disinfecting, Cutting Oils, Cooling Towers and Hard Surface Disinfection/Sanitization of Food Processing Equipment.

1. Prior to sanitization or disinfectant treatments, thoroughly clean all surfaces/areas to be treated with a suitable detergent followed by a clean potable water rinse. Remove all gross food particles and filth using appropriate methods such as spray, dip, soak, wash, pre-flush, pre-scrape or pre-soak.
2. When preparing activated solutions: Prepare only in well-ventilated area. Avoid breathing fumes produced while activator is dissolving. Allow 15 minutes' reaction time. As an alternate activation method, adjust the pH to 4.0 with acetic, citric, phosphoric, sulfuric or hydrochloric acid; or add 0.25 to 0.5 grams of DRA-2 per gallon of water.
3. When spraying or fogging disinfectant/sanitizing solutions: Solutions may be irritating when inhaled. During spraying or fogging operations wear a NIOSH/MSHA-approved respirator appropriate for chlorine dioxide. Do not reuse activated solutions; apply only freshly-made solutions for disinfection or sanitization.
4. Chemical feed pumps and injectors must be chlorine-resistant for best operation. To extend freshness and shelf life, confirm available chlorine dioxide levels using a SaniCide™ test kit, available from ConSeal.

Mushroom and Vegetable Processing and Canning Operations

Product Data

In Mushroom Facilities, such as mushroom production, spawn productions, mushroom processing and cannery operations: Use as a terminal sanitizing rinse for stainless steel tanks, transfer lines, on-line equipment, picking baskets, picking utensils and other food contact surfaces.

1. Preparation of sanitizing solution: In a clean plastic container mix 3¼ fl. oz. of **SaniCide™-2** with 5 gallons of clean potable water and 1.2 grams of DRA-1. This solution will yield a working solution containing 100 ppm available chlorine dioxide.

2. To apply: Flush picking baskets, line equipment or other food contact surfaces with active solution, making sure surface area is thoroughly wet for at least 1 minute. After sanitizing, drain treated baskets or equipment and allow to air dry. Treat after each use or production run. Discard solution after each use.

To Disinfect Walls, Ceilings and Floors:

1. Preparation of active disinfecting solution: Per gallon of working solution mix, in a clean plastic container, 3¼ fl. oz. of **SaniCide™-2** with 1 gallon of clean potable water and 1.2 grams of DRA-1. This will yield a working solution containing 500 ppm available chlorine dioxide.
2. To apply: Spray disinfectant solution onto surfaces using a suitable spraying device and making sure that the area is thoroughly wet for at least 10 minutes. After application, allow treated surfaces to air dry. Treat as required.

To Control Mold- and Slime-Forming Bacteria on Walls, Floors, Ceilings and Post-Crop Mushroom Growing Surfaces:

1. Preparation of solution: Per gallon of working solution mix, in a clean plastic container, 6½ fl. oz. of **SaniCide™-2** with 1 gallon of clean potable water. This will yield a working solution containing 1,000 ppm available chlorine dioxide.
2. To apply: During application treatment area must be closed as tightly as possible and sealed. Drench, or spray ~~or fog~~ solution on walls, floors, ceilings and post-crop mushroom growing surfaces using a suitable watering, or spraying ~~or fogging~~ device, making sure all surface areas are thoroughly wet. After spraying or drenching ~~or fogging~~, open the treatment area and ventilate for 1 hour before re-entry. Allow all treated surfaces to air dry. Avoid contact with food or food contact surfaces. Repeat application as needed.

To Control the Buildup of Odor- and Slime-Forming Bacteria in Process Waters for Vegetable Rinses and Associated Tanks, Flumes and Lines:

1. Preparation of solution: Prepare **SaniCide™-2** solutions daily. Chill tanks or vegetable rinse tanks may be batch-loaded at startup with 1/3 fl. oz. (10 ml) **SaniCide™-2** per 10 gallons of potable water. This will yield a working solution containing 5 ppm available chlorine dioxide. Treat make-up waters with a chemical feed pump or injector system and apply **SaniCide™-2** at the rate of 1/3 fl. oz. per 10 gallons of potable water.
2. Optional activated solution: If heavy use of rinse water is expected or if slime buildup is extreme, an additional activation step may be used in preparation of the solution.
3. Preparation of activated solution: For each 10 gallons of rinse water to be used mix, in a clean plastic container, 1/3 oz. (10 ml) of **SaniCide™-2** with 1 gallon of water and 8 grams (1/4 oz.) of DRA-1 (or 4 grams (1/8 oz.) of DRA-2). Allow this solution to stand for 15 minutes then add 9 gallons of water to yield a solution containing 5 ppm available chlorine dioxide.
4. Chill tanks or vegetable rinse tanks may be batch-loaded at startup with activated **SaniCide™-2** solution by mixing 1/3 fl. oz. (10 ml) **SaniCide™-2** with 10 gallons of potable water. This will yield a working solution containing 5 ppm available chlorine dioxide. Treat make up waters with a chemical feed pump. To ensure accurate delivery, prepare a 1 to 10 dilution of the active concentration and maintain the feed rate of this dilution at 3-1/3 fl. oz. per 10 gallons.

For Use in the Preparation of Fruits and Vegetables to Extend Freshness and Shelf-Life:

1. Wash whole fruits and vegetables then rinse with clean potable water.
2. To 1 gallon of water add 1/3 fl. oz. (10 ml) of **SaniCide™-2** and 1 gram of DRA-1, or adjust the pH to 4 with vinegar. Allow solution to stand for 15 minutes then add to 9 gallons of water.
3. As a pretreatment for uncut, unpeeled fruits and vegetables, dip produce in solution for approximately 10 to 20 seconds, then rinse with potable water.

Biological Control in Paper Mills, Food Processing Flumes, Water Treatment Equipment, Petroleum Recovery, Hospital Disinfecting, Cutting Oils, Cooling Towers, Hard Surface Disinfection/Sanitization of Food Processing Equipment

Product Data

To Disinfect Walls, Ceilings and Floors:

1. Add 2.5 fl. oz. of **SaniCide™-2** per gallon of solution to be used (1:51 dilution). Adjust the pH of the solution to 4 with acetic acid (vinegar), citric acid, phosphoric acid or add ¼ up to ½ (0.25 up to 0.5) grams of DRA-2 to each gallon of solution. Allow to stand for 15 minutes.
2. Spray or fog the above solution onto surfaces to be disinfected. Allow surfaces to remain wet for at least 20 minutes then air dry. Apply only freshly prepared solutions.
3. For sink soaking of previously cleaned utensils, heavily stained dishes, glasses and equipment parts, prepare the solution as described above. Fill and hold for 20 minutes. Drain and air dry.

To Control the Buildup of Odor and Slime and Improve Taste in Ice Plants and Poultry/Meat Processing Plant Water:

1. Thoroughly clean ice making machinery with a detergent solution followed by a potable water rinse.
2. Meter into the incoming water to the ice plant potable water system 1 gallon of **SaniCide™-2** per 1,000 gallons of water (20 ppm available chlorine dioxide).
3. As an additive to potable water in meat and poultry processing plants to inhibit bacterial slime and improve taste and odor, add 1 gallon of **SaniCide™-2** per 1,000 gallons of water.

To Control Odor- and Slime-Forming Bacteria, Mold and Mildew on Walls, Floors and Ceilings:

1. Dilute 2.5 gallons of **SaniCide™-2** to 20 gallons water (2,500 ppm available chlorine dioxide). Spray or soak the walls, floors and ceilings with this solution. Allow to air dry and repeat as necessary. Avoid contact with food.

To Inhibit Bacterial Slime-Forming Bacterial Buildup in Commercial Water Filtration Systems, Sand Beds, Gravel Beds, Charcoal Filters and Cooling Water Systems:

Filters:

1. Carefully back flush filters with potable water, where possible, to remove all accumulated solid residue and contamination.
2. Fill system with potable water and adjust the pH to 6.0 with citric acid, phosphoric acid or acetic acid (vinegar).
3. Add 2 fl oz. of **SaniCide™-2** per gallon of filter system volume (300 ppm) to the accumulation tank and circulate the system for 1 hour. Check the pH and adjust back to 6.0 if it has drifted. Bring the chlorine dioxide concentration back to 300 ppm.
4. Circulate the solution for 1 additional hour, discharge and then water wash for 30 minutes with potable water to remove the chlorine dioxide.

Cooling Water Systems:

1. Weekly, add 2.5 gallons of **SaniCide™-2** per 10,000 gallons of cooling water.
2. Depending upon the degree and type of contamination, addition frequency may be reduced to every 2 to 3 weeks when contamination is under control.

In Industrial Applications to Inhibit the Growth of Slime- and Odor-Causing Bacteria in Water-Based Cutting Oils:

1. Batch Method: Add 80 fl. oz. of **SaniCide™-2** per 1,000 gallons to fresh systems and repeat weekly or at first indication of increased bacterial contamination (odor, slime, bacterial count). Alkaline systems may require a higher concentration of **SaniCide™-2**.
2. Continuous Method: Proportion in 5 gallons of **SaniCide™-2** per million gallons per day used in the system. Alkaline systems may require a higher concentration of **SaniCide™-2**.
3. Badly Contaminated Systems: Slug dose system with 25 gallons of **SaniCide™-2** per million gallons of cutting oil. Then start the continuous procedure described above.

4. Adjust quantities in any of the above systems to compensate for levels of contamination, pH, type of contamination, etc. as necessary.

To Prevent Corrosion and Slime Bacteria in Oil Wells During Secondary Recovery Operations:

1. Prepare a working solution of 5,000 ppm stabilized chlorine dioxide by diluting each gallon of **SaniCide™-2** used to 4 gallons solution with the injection water.
2. Proportion 1 part of the above solution into each 150 parts of reinjected acidified (3.0 to 4.0 pH) water.
3. Monitor microbial content of the water and increase or decrease the addition rate of the working solution as necessary.

In Food Processing Plants (Poultry, Meat, and Fish), Dairies and Bottling Plants:

For use as a terminal food contact surface sanitizing rinse conforming to 21 CFR 178.1010(b)(34) and (c)(29) not requiring a subsequent potable water rinse.

1. This solution is intended for use as a food contact surface sanitizer for dairies, ice cream factories and food processing plants.
2. This solution may be used on hard surfaces such as tables, trays, bins, etc. and the interior or exterior of food processing equipment.
3. Thoroughly clean all equipment to remove gross food particles and soil by a pre-flush, pre-scrape and, where necessary, a pre-soak treatment. Clean surfaces or objects with a detergent or cleaner followed by a potable water rinse prior to applying sanitizing solution.
4. The active biocide in the system is free chlorine dioxide, even though the stabilized chlorine dioxide at pH 8.5 is mildly bacteriostatic. Free chlorine dioxide is released by the addition of an activator and/or acidulant. Prepare a solution containing 1,000 ppm of total available chlorine dioxide by adding 2.5 gallons of **SaniCide™-2** per 50 gallons of water and 64 grams (2.3 ounces) of DRA-2. Agitate 5 minutes and allow to stand for 15 minutes. Alternatively, activate the solution by adding food grade citric acid, phosphoric acid or acetic acid (vinegar) to pH 4.0. Dilute 1 part of this solution with 4 parts water to provide 200 ppm total chlorine dioxide and approximately 125 ppm free chlorine dioxide (30 to 40 ppm free chlorine dioxide, when acid activation is used).
5. Allow this solution to contact all food processing equipment for at least 1 minute, but preferably longer, by transferring and/or spraying into each food processing vessel. It is essential that the sanitizing solution contact all surfaces to be sanitized; thus, fill hard to reach in-place equipment, pipes, closed vessels, etc. with the solution to ensure contact of all surfaces with the sanitizing solution.
6. After the required contact time (or longer), allow solution to drain from all surfaces and air dry.
7. The above solution may not be reused for sanitizing but may be diluted 1:5 with water and used for cleaning plant walls, floors and drains.

As a Slimicide in Paper Mills to Prevent Slime, Tar Spots and Pitch Spots in White Water Systems:

By maintaining a chlorine dioxide atmosphere in the white water the microorganisms cannot produce the nodules that result in slime.

1. If the pH of the white water is below 7.0, add 11¼ gallons of **SaniCide™-2** per hundred tons of paper produced.
2. If the pH of the white water is above 7.0, then add ½ gallon of 50% sodium hypochlorite as an activator with each 11¼ gallons of **SaniCide™-2**.
3. For best results continuously proportion the **SaniCide™-2** feed. In many cases, the **SaniCide™-2** amount may be reduced after the system is clean.

Storage and Disposal

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Do not store with easily oxidizable materials, acids, reducers or combustible materials. Avoid heat or freezing conditions. Store upright and do not stack drums over two high on pallets or partially filled drums.

Use of a drum pump is suggested. Keep drum tightly closed when not withdrawing liquid. In case of spills, dilute with large quantities of water. Do not allow liquid to dry; this could present a fire hazard. Store only in original container and take care to prevent cross-contamination with fertilizers, food, feed or other pesticides. **Pesticide Disposal:** Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label directions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance. **Container Disposal:** Non-refillable container; do not reuse or refill this container. Triple rinse (or equivalent) container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times.

{Per PR Notice 2007-4 the batch code/lot number will appear on the label or container.}

Emergency Handling

In case of contamination or decomposition, do not reseal container; isolate in an open, well-ventilated area and flood with large volumes of water. Cool unopened drums in vicinity by water spray.

Notice: Seller expressly warrants that the product conforms to its chemical description. To the extent consistent with applicable law, there are no warranties associated with the sale of this product, either express or implied, including but not limited to, the warranties of fitness for a particular purpose or use.



NSF International certifies that this product conforms to the requirements of ANSI/NSF Standard 60 – Drinking Water Treatment Chemicals – Health Effects with maximum use levels for potable water of 10 ppm.

ConSeal International, Inc.
90 Kerry Place, Suite 2
Norwood, MA 02062
(781) 278-0010

[] Denotes alternate/optional language
{ } Denotes language that does not appear on the market label.